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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,098	06/25/2003	Upul K. Bandarage	102258.154US1	1938

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EXAMINER

STOCKTON, LAURA

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/603,098

Applicant(s)

BANDARAGE ET AL.

Examiner

Laura L. Stockton, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 3-13, 17-27, 40-54 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 14-16, 28-39 and 55-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/18/04 & 8/23/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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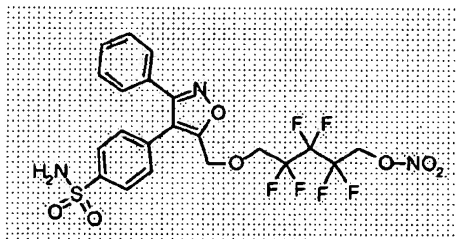
DETAILED ACTION

Claims 1-58 are pending in the application.

Election/Restrictions

Applicants' election with traverse of Group IV (claims 1, 2, 14-16, 28-39 and 55-57) and the species of Example 34 on page 99 (see structure below) in the reply filed on January 10, 2005 is acknowledged. Note, Claims 56 and 57 were inadvertently left out of Group IV (as well as Groups I-III) in the Restriction Requirement.

Example 34: 4-(5-((2,2,3,3,4,4-Hexafluoro-5-(nitrooxy)pentyl)oxy)methyl)-3-phenylisoxazol-4-yl)benzenesulfonamide



The traversal is on the ground(s) that: (1) all of the pending claims are related; (2) none of the three

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criteria for distinctness have been shown; (3) if the nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds are allowable, then all the kits and methods of use for these compositions are allowable; and (4) a search of the prior art for the nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor compounds and compositions would encompass a search of the prior art for their methods of use and kits comprising the compounds.

Applicants' arguments have been considered but have not been found persuasive. Elected Group IV is directed to products that may or may not be nitrosated and/or nitrosylated (see definition of the V variable; and the species in claim 55 on page 136, line 4). As stated in the Restriction Requirement dated December 10, 2004, the products are properly restrictable from the methods of use and kit since the process for using the product as claimed can be

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practiced with another materially different product. Additionally, if the products are found allowable, the methods of use are not automatically allowable. The method of use claims would have to be evaluated for 35 USC § 112, first and second paragraph matters. In regard to Applicants' statement concerning prior art, different search considerations are involved for each of the outlined groups. A reference that anticipates the products may not even render the method of use obvious. Therefore, it would impose an undue burden on the Examiner and the Patent Office's resources if the instant application were not restricted.

Additionally, in accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper.

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Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

The requirement is still deemed proper and is therefore made FINAL.

Subject matter not embraced by elected Group IV and Claims 3-13, 17-27, 40-54 and 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions. Applicant timely traversed the restriction (election) requirement in the reply filed on January 10, 2005.

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It is suggested that in order to advance prosecution, the non-elected subject matter be canceled when responding to this Office Action.

Information Disclosure Statement

The Information Disclosure Statements filed on June 18, 2004 and August 23, 2004 have been considered by the Examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 14-16 and 28-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim

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the subject matter which applicant regards as the invention.

In claim 1, under the definition of R_4 and R'_4 , an "or" is needed before "alkoxy" (page 123, line 10). In claim 1, under the definition of R_a , a comma is needed after "electron" (page 123, line 19). In claim 1, under the definition of R_i , an "or" is needed before " $-(N_2O_2)^- \cdot M^+$ " (page 123, line 25).

Claim 32 does not conform to M.P.E.P. 608.01(m) since each claim must end with a period and no other periods may be used elsewhere in the claims except for abbreviations (page 129, line 4).

In claim 36, the phrase "wherein compound comprising" should be changed to "wherein the compound comprising" (page 130, line 19). In claim 36, the additional comma after "oligonucleotide" should be deleted since it appears that something is missing (page 130, line 23).

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 14-16, 28-35, 37-39 and 55-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Talley {U.S. Pat. 5,859,257}.

Talley discloses compounds of Example 56 (column 85) and Example 60 (column 88), which are embraced by the instant claimed invention. Therefore, the instant claimed invention is anticipated by Talley.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 14-16, 28-39 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talley {U.S. Pat. 5,859,257}, taken alone, or in combination with Bandarage et al. {U.S. Pat. 6,297,260}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim isoxazole compounds of Formula (III). Talley teach isoxazole compounds that are either structurally the same as (see above 102 rejection) or structurally similar to the instant claimed compounds. See in Talley {column 6, lines 51-67; column 7, lines 1-43; and column 8, lines 1-31},

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for example, Formula II wherein R⁴ is aryl and R⁵ is amino and R⁶ is (hydroxy)alkoxyalkyl. Also see column 2, lines 64-67; column 3; column 4, lines 1-56; columns 98-100; and especially Example 56 in column 85, and Example 60 in column 88.

Ascertainment of the difference between the prior art and the claims
(MPEP §2141.02)

The difference between some of the compounds of Talley and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP
§2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar

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compounds would possess similar activity (e.g., an anti-inflammatory). Additionally, Bandarage et al. {column 2, lines 19-46; column 10; column 15; column 17; column 18; and column 30, lines 8-58} teach administering a composition which has at least one nitric oxide donor to prevent, reduce or reverse gastrointestinal, renal, and other toxicities induced by nonsteroidal anti-inflammatory drugs {NSAID}.

One skilled in the art would thus be motivated to prepare compounds embraced by Talley, and especially in view of the teaching of Bandarage et al., to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful in treating inflammation. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

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The elected species of Example 34 is allowable over the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, reading "Laura L. Stockton". The signature is fluid and cursive, with the first name "Laura" and last name "Stockton" clearly distinguishable.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

March 17, 2005